

Gregg-Smith-Collins Safe IMPORT Act

Safe Importing of Medical Products and Rx Therapies Act

The **Safe IMPORT Act** allows individuals, pharmacies, and wholesalers to safely import FDA-approved Rx drugs from Canada and from as many as 15 other Western European countries.

Personal Importation

For the first time, individuals will be able to legally import prescription drugs for their personal use.

- Individuals with a valid prescription can personally import up to a 90-day supply of FDA-approved prescription drug products.
- The drug may be purchased from a licensed pharmacy in Canada or another permitted country.
- As permitted under current FDA policy, unapproved products may be imported under a “compassionate use” exemption to continue medical treatment for a serious medical condition begun overseas.

Pharmacy, Wholesaler & Internet Importers

Allows importation of commercial quantities of prescription drug by pharmacies and wholesalers, and ensures that Internet pharmacies are legitimate, licensed, and accountable.

- Protects consumers from rogue Internet pharmacies by establishing federal licensing requirements and penalties for all Internet pharmacies that conduct or solicit business in the U.S.
- All Internet pharmacies required to demonstrate that they comply with all existing Federal, State, and local regulations governing the practice of medicine and pharmacy.
- Establishes registration and pedigree requirements to ensure that prescription drugs imported by pharmacies and sold to American consumers are safe.
- Ensures that the FDA has sufficient resources to monitor the safety of imported Rx drugs by establishing a new “user fee” program for all businesses engaged in importation.

Ensures Products are Safe

Ensures that imported drugs are safe and effective, and consistent with the FDA gold standard.

- Allows importation of FDA-approved products manufactured in FDA-approved facilities.
- FDA will have similar authority over imported drugs as they have in ensuring the safety of imported food:
 - ▶ Registration. All foreign businesses in Canada and permitted countries engaged in the importation of Rx drugs to the U.S. will be required to register with the FDA.
 - ▶ Prior notice. Persons importing Rx drugs into the U.S. will be required to identify the port of entry and give the FDA prior notice of any commercial shipment.

- ▶ Detention, suspension, and debarment. FDA will have the authority to detain, suspend, or bar the importation of individual Rx drugs, all drugs from individual companies, and importation from an entire country if necessary to protect the public health.
 - ▶ Marking, port shopping. FDA will have the authority to mark unsafe Rx drugs and prevent them from entering the U.S. through a different port.
 - ▶ Recordkeeping. To prevent the sale of counterfeit and unsafe Rx drugs, all domestic pharmacists, wholesalers, and others along the supply chain must maintain a pedigree of the immediate previous source and immediate subsequent recipient of a Rx drug, regardless of whether the drug is imported. As an additional safety measure, a prescription drug imported from Canada must be accompanied by a pedigree that identifies all of the previous members of the supply chain.
- All foreign businesses in Canada and permitted countries engaged in the importation of Rx drugs to the U.S. will be required to submit to FDA inspections.
 - Authorizes the FDA to develop new guidelines for the sale and distribution of prescription drugs to reduce the likelihood of counterfeit and unsafe drugs entering the market place and establish a Counterfeit Alert Network to notify health professionals and the public if they do.

Effective Dates

Provisions allowing for personal importation of prescription drugs from Canada will become effective immediately.

- Pharmacy & wholesaler importation provisions become automatically effective within one year.
- Internet pharmacy provisions will become effective upon issuance of final regulations, which FDA must complete within one year.
- Two years after the pharmacy and wholesaler importation provisions become effective, FDA may permit importation from countries that were members of the European Union prior to December 31, 2003.